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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/727,092	12/02/2003	Michael F. Mullarkey	5012-US-CNT	5999

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EXAMINER	
ROMEO, DAVID S	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/727,092	MULLARKEY, MICHAEL F.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-11* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-18* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1–18 are pending.

Election/Restrictions

Applicant's election without traverse of group V, claims 12–18 in the reply filed on 03/06/2007 is acknowledged.

Claims 1–11 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 03/06/2007.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

This application is claiming the benefit of prior-filed nonprovisional application No. 07/776,624 under 35 U.S.C. 120, 121, or 365(c). Copendency between the current application and the prior application is required. Since the applications are not copending, the benefit claim to the prior-filed nonprovisional application is improper. Applicant is required to delete the reference to the prior-filed application from the first sentence(s) of the specification, or the application data sheet, depending on where the reference was originally submitted, unless applicant can establish copendency between the applications.

U. S. Application Nos. 07/776,624 and 08/211,667 are not copending because 07/776,624 became abandoned before 08/211,667 was filed. Accordingly, the effective filing date of the current application is 04/14/1994, the filing date of 08/211,667.

Further with respect to the request for correction of continuing data information, filed 04/30/2004, it is noted that the filing date of U. S. Application No. 09/048,815 should have been 03/26/1998.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 12–13 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith (U. S. Patent No. 5,395,760).

Smith teaches a soluble TNF-R molecule which retains its ability to bind TNF (column 9, full paragraph 1), therapeutic compositions comprising an effective amount of soluble TNF-R proteins and physiologically acceptable carriers, excipients or diluents, and methods for suppressing TNF-dependent inflammatory responses in humans comprising administering an effective amount of soluble TNF-R protein (column 16, last paragraph, through paragraph bridging columns 16-17). Purified TNF receptor compositions may be used directly in therapy to bind or scavenge TNF, thereby providing a means for regulating the immune activities of this cytokine (paragraph bridging columns 2-3).

The "adapted for" clause does not limit claim 12 to a particular pharmaceutically acceptable carrier. In the absence of evidence to the contrary, Smith's physiologically acceptable carriers, excipients or diluents are "adapted for topical or parenteral application."

Claims 12–16 are rejected under 35 U.S.C. 102(e) as being anticipated by Troutt (U. S. Patent No. 6,083,906).

The effective filing date of Troutt is 04/09/1990, which is obtained via U. S. Application No. 07/507,213.

Troutt teaches compositions comprising preferred immunoregulatory molecules that are fusion proteins of soluble IL-1 receptors and soluble TNF receptors and neutral buffered saline (column 13, full paragraph 5 through column 14, full paragraph 1).

The "adapted for" clause does not limit claim 12 to a particular pharmaceutically acceptable carrier. In the absence of evidence to the contrary, neutral buffered saline, or any of the other physiologically acceptable carriers, excipients or diluents disclosed by Troutt at column 13, full paragraph 5 through column 14, full paragraph 1, are "adapted for topical or parenteral application."

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 12–14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Smith (U. S. Patent No. 5,395,760) as applied to claims 12–13 above, and further in view of Brewer (U. S. Patent No. 6,143,866) and Dower (U. S. Patent No. 4,968,607).

Smith teaches a soluble TNF-R molecule which retains its ability to bind TNF, therapeutic compositions comprising an effective amount of soluble TNF-R proteins and physiologically acceptable carriers, excipients or diluents, and methods for suppressing TNF-dependent inflammatory responses in humans, as discussed above. Smith does not teach a therapeutic composition comprising a mixture of IL-1 receptors and TNF receptors.

Brewer discloses that in septic shock, acute lung injury or other circumstances in which TNF has a harmful effect, TNF inhibitors could be even more effective when administered in conjunction with interleukin-I (IL-1) inhibitors. This combination therapeutic will be especially useful in treatment of inflammatory and degenerative diseases (column 20, full paragraph 1). The examiner relies on an effective filing date of Brewer of July 19, 1990, which is obtained via U. S. Application No. 07/555,274.

Dower teaches purified IL-1 receptor compositions may be used directly in therapy to bind or scavenge IL-1, thereby providing a means for regulating the immune or inflammatory activities of this cytokine. Column 2, last full paragraph. "Interleukin-1 receptor" and "IL-1R" refer to proteins which are capable of binding Interleukin-1 (IL-1) molecules and, in their native configuration as mammalian plasma membrane proteins, presumably play a role in transducing the signal provided by IL-1 to a cell. As used herein, the term includes analogs of native proteins with IL-1-binding or signal transducing activity. Paragraph bridging columns 6-7. Recombinant IL-1R proteins within the scope of the present invention also include N-terminal methionyl murine and human IL-1Rs. Additional embodiments include soluble truncated versions wherein certain regions, for example, the transmembrane region and intracellular domains, are deleted,

providing a molecule having an IL-1-binding domain only. Column 14, full paragraph 2. The antigen (soluble IL-1R) in saline is injected intravenously (column 24, lines 50-52).

Brewer and Dower do not teach a therapeutic composition comprising a mixture of IL-1 receptors and TNF receptors. However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make a therapeutic compositions comprising an effective amount of soluble TNF-R proteins, as taught by Smith, and to modify that teaching by making a therapeutic composition comprising a mixture of IL-1 receptors and TNF receptors, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because TNF inhibitors could be even more effective when administered in conjunction with interleukin-I (IL-1) inhibitors, this combination therapeutic will be especially useful in treatment of inflammatory and degenerative diseases, and a soluble IL-1 receptor, as taught by Dower, is an IL-1 inhibitor.

The invention is prima facie obvious over the prior art.

Claims 12–17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Palladino (U. S. Patent No. 5,055,447) in view of Troutt (U. S. Patent No. 6,083,906) and Ralph (U. S. Patent No. 5,567,611).

Palladino teaches a composition for the treatment or prevention of septic shock comprising a corticosteroid, an antagonist to tumor necrosis factor, an antagonist to interleukin-1 (column 4, last paragraph), and a carrier vehicle such as saline (column 7, full paragraph 3).

Palladino does not teach a therapeutic composition comprising a corticosteroid and fusion protein of a soluble IL-1 receptor and a soluble TNF receptor.

Troutt teaches compositions comprising preferred immunoregulatory molecules that are fusion proteins of soluble IL-1 receptors and soluble TNF receptors and neutral buffered saline (column 13, full paragraph 5 through column 14, full paragraph 1).

Ralph teaches that the joining of two or more coding sequences having independent functions or bioactivities has the added advantage of creating a larger molecule with potential for a longer in vivo half-life resulting in increased efficacy (column 12, lines 27-38).

Trout and Ralph do not teach a therapeutic composition comprising a corticosteroid and a fusion protein of a soluble IL-1 receptor and a soluble TNF receptor.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make a composition comprising a corticosteroid, an antagonist to tumor necrosis factor, an antagonist to interleukin-1, as taught by Palladino, and to modify that teaching by making a composition comprising a corticosteroid and fusion protein of a soluble IL-1 receptor and a soluble TNF receptor, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because the joining of two or more coding sequences having independent functions or bioactivities has the added advantage of creating a larger molecule with potential for a longer in vivo half-life resulting in increased efficacy.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12–13 and 16–18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a soluble TNF receptor which is capable of binding TNF, does not reasonably provide enablement for a TNF receptor analog which is capable of binding either IL-1 or TNF. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to or encompass a TNF receptor analog which is capable of binding either IL-1 or TNF. There are no structural limitations to the analogs. The claims encompass essentially any compound capable of binding either IL-1 or TNF, including compounds that are structurally unrelated to the native TNF receptor. The specification lacks guidance for making and working examples of structurally unrelated compounds with the desired activity. Moreover, there is a lack of predictability in the art. Predicting structure, hence function, from primary amino acid sequence data is extremely complex and there doesn't exist an efficient algorithm for predicting the structure of a given protein from its amino acid sequence alone. See Bowie (Science, (1990 Mar 16) 247 (4948) 1306-10) page 1306, column 1, full paragraph 1 or Ngo (The Protein Folding Problem and Tertiary Structure Prediction, Merz and Le Grand (Eds), August 1994, Springer Verlag) page 433, full paragraph 1, and page 492, full paragraph 2.

Furthermore, there are no working examples of a TNF receptor that binds IL-1. The examiner is aware working examples are not required. Lack of a working example is, however, a factor to be considered.

The skilled artisan is left to extensive experimentation, wherein compounds are randomly made and through trial and error experimentation is left to determine which are capable of binding either IL-1 or TNF. Such extensive, random, trail and error experimentation is considered undue. In view of the breadth of the claims, the limited amount of direction and working examples provided by the inventor, the unpredictability in the art and the quantity of experimentation needed to make or use the invention based on the content of the disclosure, it would require undue experimentation for the skilled artisan to make and/or use the full scope of the claimed invention.

Claims 12 and 14–18 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a therapeutic composition comprising a soluble TNF receptor, does not reasonably provide enablement for a therapeutic composition comprising a TNF receptor. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The claims are directed to or encompass a therapeutic composition comprising a TNF receptor and a pharmaceutically acceptable carrier. The terms "therapeutic" and "pharmaceutically" encompass and/or imply preventing, diagnosing, alleviating, treating, or curing a disease or condition in a mammal.

TNF receptor (TNF-R) proteins are expressed on the plasma membrane of a TNF-responsive cell and comprise a transmembrane region. See Smith (U. S. Patent No. 5,395,760), column 1, lines 31-34; column 3, lines 10-35. Alberts discloses that when the detergent is

removed, solubilized membrane proteins usually become highly insoluble and precipitate (paragraph bridging pages 265-266). The naked membrane protein molecules tend to bury their hydrophobic regions by clustering together, forming large aggregates that precipitate from solution (page 266, Figure 6–19). Therefore, it is reasonable to assume that the native TNF receptor would be highly insoluble and precipitate, forming large aggregates that precipitate from solution. Aggregation may not only reduce activity but also be problematic when preparing pharmaceutical formulations, because aggregates can be immunogenic. See Hastings (U. S. Patent No. 5,871,969), column 12, last full paragraph. Accordingly, the specification has not enabled a pharmaceutical composition comprising a TNF receptor as broadly claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 16 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 16 recites the limitation "said receptor analogues" in line 2. There is insufficient antecedent basis for this limitation in the claim. Claim 16 depends from claim 14. Claim 14 is limited to TNF receptors and does not encompass receptor analogues.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 12–13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1–4 of U.S. Patent No. 6,201,105 in view of Smith (U. S. Patent No. 5,395,760).

The TNF receptor of the present claims is generic to and fully encompasses the TNF receptor of the patent's claims. Claims 1–4 of U.S. Patent No. 6,201,105 do not teach a pharmaceutical composition comprising the TNF receptor of the patent's claims.

Smith teaches a soluble TNF-R molecule which retains its ability to bind TNF (column 9, full paragraph 1), therapeutic compositions comprising an effective amount of soluble TNF-R proteins and physiologically acceptable carriers, excipients or diluents, and methods for suppressing TNF-dependent inflammatory responses in humans comprising administering an effective amount of soluble TNF-R protein (column 16, last paragraph, through paragraph bridging columns 16-17). Purified TNF receptor compositions may be used directly in therapy to bind or scavenge TNF, thereby providing a means for regulating the immune activities of this cytokine (paragraph bridging columns 2-3).

It would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make a pharmaceutical composition comprising the TNF receptor of the patent's claims with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification in order to suppress TNF-dependent inflammatory responses in humans. The recitation of "for treating allergic responses" is an intended use of the claimed composition and does not result in a structural difference between the claimed composition and the pharmaceutical composition suggested by the prior art. The "adapted for" clause does not limit claim 12 to a particular pharmaceutically acceptable carrier. In the absence of evidence to the contrary, any of the physiologically acceptable carriers, excipients or diluents in the prior art are "adapted for topical or parenteral application."

Claims 12–16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1–4 of U.S. Patent No. 6,201,105 in view of Smith (U. S. Patent No. 5,395,760) as applied to claims 12–13 above, and further in view of Brewer (U. S. Patent No. 6,143,866), Troutt (U. S. Patent No. 6,083,906) and Ralph (U. S. Patent No. 5,567,611).

Claims 1–4 of U.S. Patent No. 6,201,105 in view of Smith teach a pharmaceutical composition comprising the TNF receptor of the patent's claims, as discussed above. Claims 1–4 of U.S. Patent No. 6,201,105 in view of Smith do not teach not teach a therapeutic composition comprising a mixture of IL-1 receptors and TNF receptors.

Brewer discloses that in septic shock, acute lung injury or other circumstances in which TNF has a harmful effect, TNF inhibitors could be even more effective when administered in

conjunction with interleukin-I (IL-1) inhibitors. This combination therapeutic will be especially useful in treatment of inflammatory and degenerative diseases (column 20, full paragraph 1). The effective filing date of Brewer of July 19, 1990, which is obtained via U. S. Application No. 07/555,274.

Troutt teaches compositions comprising preferred immunoregulatory molecules that are fusion proteins of soluble IL-1 receptors and soluble TNF receptors and neutral buffered saline (column 13, full paragraph 5 through column 14, full paragraph 1). The effective filing date of Troutt is 04/09/1990, which is obtained via U. S. Application No. 07/507,213.

Ralph teaches that the joining of two or more coding sequences having independent functions or bioactivities has the added advantage of creating a larger molecule with potential for a longer in vivo half-life resulting in increased efficacy (column 12, lines 27-38).

Brewer, Troutt, and Ralph do not teach a therapeutic composition comprising a fusion protein of a soluble IL-1 receptor and a soluble TNF receptor.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make a therapeutic composition comprising a mixture of IL-1 receptors and TNF receptors, as taught by claims 1–4 of U.S. Patent No. 6,201,105 in view of Smith, and to modify that teaching by making a composition comprising a fusion protein of a soluble IL-1 receptor and a soluble TNF receptor, with a reasonable expectation of success. One of ordinary skill in the art would be motivated to make this modification because the joining of two or more coding sequences having independent functions or bioactivities has the added advantage of creating a larger molecule with potential for a longer in vivo half-life resulting in increased efficacy. The invention is prima facie obvious over the prior art.

Claims 12–17 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1–4 of U.S. Patent No. 6,201,105 in view of Smith (U. S. Patent No. 5,395,760) as applied to claims 12–13 above, and further in view of Brewer (U. S. Patent No. 6,143,866), Troutt (U. S. Patent No. 6,083,906) and Ralph (U. S. Patent No. 5,567,611) as applied to claims 12–16 above and further in view of Palladino (U. S. Patent No. 5,055,447).

Claims 1–4 of U.S. Patent No. 6,201,105 in view of Smith and further in view of Brewer, Troutt, and Ralph teach a composition comprising a fusion protein of a soluble IL-1 receptor and a soluble TNF receptor, as discussed above. Claims 1–4 of U.S. Patent No. 6,201,105 in view of Smith and further in view of Brewer, Troutt, and Ralph do not teach a composition comprising a fusion protein of a soluble IL-1 receptor and a soluble TNF receptor and a corticosteroid.

Palladino teaches a composition for the treatment or prevention of septic shock comprising a corticosteroid, an antagonist to tumor necrosis factor, an antagonist to interleukin-1 (column 4, last paragraph), and a carrier vehicle such as saline (column 7, full paragraph 3). Palladino does not teach a therapeutic composition comprising a corticosteroid and fusion protein of a soluble IL-1 receptor and a soluble TNF receptor.

However, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to make a composition comprising a fusion protein of a soluble IL-1 receptor and a soluble TNF receptor, as taught by Claims 1–4 of U.S. Patent No. 6,201,105 in view of Smith and further in view of Brewer, Troutt, and Ralph, and to modify that teaching by making a therapeutic composition comprising a fusion protein of a soluble IL-1 receptor and a soluble TNF receptor and a corticosteroid, with a reasonable expectation of success. One of

ordinary skill in the art would be motivated to make this modification in order to treat septic shock. The invention is prima facie obvious over the prior art.

Claims 12–13 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1–52 of U.S. Patent No. 5,945,397. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are generic to and fully encompass the claims of the patent.

Claims 12–16 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 9–21 of U.S. Patent No. 6,541,610. Although the conflicting claims are not identical, they are not patentably distinct from each other because the present claims are generic to and fully encompass the claims of the patent.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISORS, JANET ANDRES OR GARY NICKOL, CAN BE REACHED ON (571)272-0867 OR (571)272-0835, RESPECTIVELY.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE HTTP://PAIR-DIRECT.USPTO.GOV. CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

DSR
MAY 26, 2007